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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,888

03/23/2007

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4033. 3004 US

8755

38473 7590 08/19/2008  
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EXAMINER

HEINCER, LIAM J

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

08/19/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,888	<b>Applicant(s)</b> WHITE ET AL.	
	<b>Examiner</b> Liam J. Heincer	<b>Art Unit</b> 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7-9 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-9 and 10-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 15, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Langer et al. (US Pat. 6,224,893).

Considering Claim 7, 15, and 18: Langer et al. teaches a method of making a semi-interpenetrating network (3:10-15) which comprises a crosslinked chitosan (6:45-50) and anionic hyaluronic acid (4:50-5:2). Langer et al. teaches a mixture of ionically crosslinkable compounds/hyaluronic acid and a covalently crosslinkable compounds/chitosan that forms a semi interpenetrating network (10:8-20). The selective crosslinking would be done by selectively adding covalent cross-linking agents (6:46-54). Since Langer et al. teaches the ionic compound as not being crosslinked, the reaction conditions would inherently be such that the amine groups would not be protonated, and the hydroxyl groups are not reacted, as these would result in the crosslinking of the hyaluronic acid.

Considering Claim 19: Langer et al. teaches the network as additionally comprising other components of the extra cellular matrix (4:1-8).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langer et al. (US Pat. 6,224,893) as applied to claim 7 above.

Considering Claims 8 and 9: Langer et al. teaches the method of claim 7 as shown above.

Langer et al. does not teach the claimed pH. However, Langer et al. does teach that the pH affects the degree of crosslinking of ionically crosslinkable polymers (1:27-29). Generally, differences in reaction conditions are not sufficient to support patentability. It would have been obvious to a person having ordinary skill in the art at the time of invention to have optimized the pH through routine optimization, and the motivation to do so would have been, as Langer et al. suggests, to reduce the crosslinking of the ionic component (1:27-29), thus providing a semi-interpenetrating network which has advantageous degradation properties and enhance mechanical properties (10:8-20).

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langer et al. (US Pat. 6,224,893) as applied to claim 7 above, and further in view of Hudson et al., Chitin and Chitosan.

Considering Claims 16 and 17: Langer et al. teaches the method of claim 7 as shown above.

Langer et al. does not teach using a chitosan from the claimed group. However, Hudson et al. teaches using a partially N-acetylated chitosan with a degree of acetylation of from 45 to 55% (pg. 2, ¶13) in a cross-linked chitosan gel (pg. 8, ¶14). Langer et al. and Hudson et al. are combinable as they are concerned with the same field of endeavor, namely chitosan hydrogels. I would have been obvious to a person having ordinary skill in the art at the time of the invention to have used the partially acetylated chitosan of Hudson et al. in the composition of Langer et al., and the motivation to do so would have been, as Hudson et al. suggests, this chitosan is soluble at neutral conditions, removing the need for a neutralization step (pg. 5, ¶12).

### ***Response to Arguments***

Applicant's arguments filed May 28, 2008 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the synergy between partially acetylated chitosan and a neutral pH) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Currently there are no claims that require both partially acetylated chitosan and a neutral pH.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liam J. Heincer whose telephone number is 571-270-3297. The examiner can normally be reached on Monday thru Friday 7:30 to 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1796

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo, Ph.D./

LJH

Supervisory Patent Examiner, Art Unit 1796

July 30, 2008

14-Aug-08